K082398 #1/1

OCT 15 2008

Summary of Safety and Effectiveness

Date: September 22, 2008

Manufacturer:
DJO Surgical (legally Encore Medical, L.P.)
9800 Metric Blvd
Austin, TX 78758

Contact Person:
Teffany Hutto
Manager, Regulatory Affairs
Phone: (512) 834-6255
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Email: teffany.hutto@djosurgical.com

Product	510(k) Number, Clearance Date/ Classification	Product Code
Vitality Hip Stem	K962560 – September 19, 1996 / Class II	JDI
Keystone Modular Hip Stem	K000521 – May 10, 2000 / Class II	LPH
ALFA II (Omega II Modular Total Hip System)	K984227 –November 24, 1998 / Class II	JDI
R120 (R120 Modular Total Hip System)	K011774 – September 5, 2001 / Class II	JDI
R120 PC (R120 Modular Total Hip System)	K021822 – July 23, 2002 / Class II	JDI

Product Code	Regulation and Classification Name
JDI	Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350
LPH	Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis per 21 CFR 888.3358
LZO	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. per 2 I CFR 888.3353

Description: The modification consists of use of a ceramic femoral head with the hip stem. The material used in the ceramic femoral head is the same as other legally marketed predicate devices.

ne Vitality, Keystone, Alfa II, R120 and R120PC are all designed for total hip joint replacement.

Total and partial hip replacement is indicated for patients suffering from disability due to:

- noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- rheumatoid arthritis;
- correction of functional deformity;
- femoral fracture

These devices may also be indicated in the salvage of previously failed surgical attempts.

The Vitality and Keystone are designed for a cementless application while the Alfa II, R120, and R120PC are designed for either cemented or cementless applications.

Intended Use: DJO Surgical hip devices are intended for treatment of patients who are candidates for total hip arthroplasty per the indications for use. While hip replacements are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.

Predicate Device: Foundation Hip Stem – K955563

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same indications, materials, sterilization, and intended use.

on-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

Encore Medical, L.P.
% Ms. Teffany Hutto
Manager, Regulatory Affaris
9800 Metric Boulevard
Austin, Texas 78758

Re: K082398
Trade/Device Name: Vitality, Keystone Modular, ALFA II, R120, R120PC
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, JDI, LPH
Dated: September 22, 2008
Received: September 23, 2008

Dear Ms. Hutto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K082398

Device Name: Vitality, Keystone Modular, Alfa II, R120, R120PC

Indications for Use:

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Total and partial hip replacement is indicated for patients suffering from disability due to:

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- rheumatoid arthritis;
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This device may also be indicated in the salvage of previously failed surgical attempts.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082398